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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/583,228	05/26/2000	Pawan Seth	8674-000004	2041

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Harness Dickey & Pierce P L C  
P O Box 828  
Bloomfield Hills, MI 48303

EXAMINER

BAHAR, MOJDEH

ART UNIT PAPER NUMBER

1617

DATE MAILED: 12/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/583,228

Applicant(s)

SETH, PAWAN

Examiner

Mojdeh Bahar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 September 2002 and 24 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-14, 19-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-14, 19-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on September 23, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/583,228 is acceptable and a CPA has been established. An action on the CPA follows.

Applicant's remarks and amendment submitted 09/23/02 are persuasive to remove the rejection under 35 USA 112 in the previous office action. Examiner thanks the applicant for pointing out that methacrylic polymer, corresponding to component (b) of claim 1 of Morella is present in a weight percentage of 1-30%.

Claims 1-4, 6-14, 19-24 are examined herein on the merits.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-14, 19-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-8 and 12 of U.S. Patent No. 6,117,453. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are drawn to a coated extended release composition comprising 5-45% verapamil (as one of the possible actives), and conventional additives, see claims 1 and 8.

Although USPN 6,117,453 does not teach the particular pharmaceutical auxiliaries recited herein, the employment of known pharmaceutical excipients and additives are within the skill of the artisan and are therefore obvious.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-14, 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (USPN 5,378,474).

Morella et al. (USPN 5,378,474) teaches a substantially similar composition as those claimed herein. Morella et al. (USPN 5,378,474) teaches a sustained release pharmaceutical

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composition having a core element containing an antihypertensive agent such as Verapamil Hydrochloride, a methacrylic polymer (1-30% wt., soluble at a pH from 6-7.5 in the intestines), hydroxypropyl methylcellulose (4-20% wt.), polyethylene glycol (15-35% wt.) and a filler such as silicon dioxide (4-30% wt.), see claims 1, 2, 7 and 9 as well as Col.4, line 24. Morella et al. (USPN 5,378,474) also teaches that the active ingredient in the pharmaceutical composition reaches its maximum concentration between about 4 and about 30 hours, col. 24, claim 1 and that the bioavailability of the active agents in the pharmaceutical pellet is not compromised by food, col.7, lines 34-40.

Morella et al. (USPN 5,378,474) does not teach the particular composition containing the specific ingredients in the amounts herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the particular composition containing the specific ingredients herein in amounts herein.

One of ordinary skill in the art would have been motivated to make the composition claimed herein since a substantially similar composition is taught in the prior art. Morella et al. (USPN 5,378,474) teaches a similar composition which may contain an antihypertensive agent (including verapamil) and the excipients herein in amounts (wt. percentages) that overlap with those in the instant claims. The optimization of amounts of ingredients to be employed in a composition is considered within the skill of the artisan. The instant composition is not seen to patentably distinguish over the prior art, absent evidence to the contrary. No such evidence is seen.

***Response to Arguments***

Applicant argues that Morella requires the presence of an insoluble matrix polymer in the coating. Note that the instant claims do not exclude the inclusion of an insoluble matrix polymer since the open transition phrase "comprising" is recited in the claims.

Applicant has amended the claims to recite that the gastroresistant polymer is present at 30-80% by weight of the coating is soluble at pH above 5.5. Note that Morella meets this limitation since it teaches a methacrylic polymer (1-30% wt.) which is soluble at a pH from 6-7.5 in the intestines, see claims 1 and 7.

Dr. Seth's declaration submitted under 37 CFR 1.132 and applicant's remarks pertaining thereto have been considered but is not persuasive to remove the obviousness rejection. Dr. Seth states that the Morella composition will not substantially dissolve in the intestines, whereas the claimed invention will. Note that the claims herein require that the coating be soluble at pH above 5.5. There is no limitation that a certain percentage of the composition must be dissolved. Arguments and/or showings as to unclaimed limitations are moot.

Dr. Seth also discusses the lack of food effect as it applies to Morella. Dr. Seth states that Morella formulation avoids food effects by the very slow release of the active, whereas the invention herein provides no food effect due to release in the intestine. Note that once again, all that is required by the limitations in the claims is that there be no food effect. The reason for the absence of food effect is not a limitation in the claim, nor does it patentably distinguish the composition herein from that of the prior art.

Further please note that the showing in the declaration is not commensurate in scope with the claims. The claims are drawn to gastroresistant polymers in general, whereas the showing in the declaration is limited to few of these polymers.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
December 6, 2002

  
SREENI PADMANABHAN  
PRIMARY EXAMINER  
12/8/02